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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/350,393	07/09/1999	RAY J. WU	19603/2760(C)	7999

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/22/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/350,393

Applicant(s)

WU ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: |

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DETAILED ACTION

The Amendment filed February 27, 2002, paper no.12, has been entered.

The specification has been amended at page 13 line 16.

Claims 19-36 have been cancelled.

Claim 4 is newly amended.

Claims 1-18 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

The corrected or substitute drawings were received in the Amendment filed February 27, 2002, paper no.12.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, Paper No. 13, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 11 and 15 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant needs to provide assurance that the deposit will be maintained for a term as set forth in 37 CFR 1.806 and that all restrictions on access will be irrevocably removed upon issuance.

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The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for presenting an open Markush group is withdrawn in light of Applicant's amendment of claim 4.

Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-18 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "ABRC unit".

Applicant's arguments filed February 27, 2002, have been fully considered but they are not persuasive.

Applicant argues that the term "ABRC unit" is well known in the art, and is defined in the specification at page 11, lines 9-18. Applicant also specifically points to the use of the term in Shen et al. I, Shen et al. II, and Su et al., each of which is incorporated by reference in the present application.

The Examiner acknowledges the definition of ABRC unit set forth in the specification at page 11, lines 9-18, and the use of the term in Shen et al. I, Shen et al. II, and Su et al. However, the Examiner maintains that the use of the acronym "ABRC" in the claims is indefinite because the acronym does not clearly provide notice as to the scope of the claimed invention. It is suggested that claim 1 be amended to recite "abscisic acid responsive complex" to clarify the meaning of the acronym "ABRC".

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Claims 1-3, 10, 14 and 18 are indefinite in the use of the noun "monocot" to modify the noun "plant". It is suggested that the claims be amended to recite "monocotyledonous plant".

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is drawn to a method for conferring tolerance to salt stress and drought stress in a plant, but omits the essential step of expressing the DNA molecule that confers tolerance. Claim 1 also omits the essential step of conferring tolerance to salt stress and drought stress to the plant.

Claim 1 is indefinite in the recitation of minimal promoter. It is unclear in what way a promoter would be minimal.

Claims 2, 4-10, 14 and 18 are indefinite in the recitation of the indefinite article "a" before "method according to claim 1". It is suggested that the claims be amended to recite "The method according to claim 1".

Claim 3 is indefinite in the recitation of the indefinite article "a" before "method according to claim 2". It is suggested that the claim be amended to recite "The method according to claim 2".

Claim 5 is indefinite in the recitation of "shortened". It is unclear the extent to which the promoters would be shortened.

Claims 11-13 are indefinite in the recitation of the indefinite article "a" before "method according to claim 10". It is suggested that the claims be amended to recite "The method according to claim 10".

Claim 12 is indefinite in the recitation of "associated. The nature of the association between the plasmid and the particles is unclear.

Claims 15-17 are indefinite in the recitation of the indefinite article "a" before "method according to claim 14". It is suggested that the claims be amended to recite "The method according to claim 14".

Claim 18 is indefinite in the recitation of "regenerating the monocot plant transformed with the DNA molecule that increases tolerance to salt stress and drought stress to form a transgenic monocot plant". It is unclear how one would regenerate a transformed plant to form a transgenic plant, since the starting material is already a plant.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (Abstract 113, General Meeting of The International Program on Rice Biotechnology, September 15-17, 1997, Applicant's IDS).

The claims are drawn to a method for conferring tolerance to salt stress and drought stress in a monocotyledonous plant comprising transforming a plant with a salt stress or drought stress inducible expression cassette comprising at least one ABRC unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants.

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Wu et al. teach the production of water stress or salt stress tolerant transgenic rice plants that comprise one or two of the following genes: a barley late embryogenesis abundant protein gene (*Hva1*), a cold and salt stress resistance gene (*COR47*), a mannitol 1-P dehydrogenase gene (*mtlD*), a gene encoding a proline biosynthesis enzyme (*P5CS*). Constitutive or ABA-inducible promoters were used to drive these genes. Although Wu et al. do not explicitly teach an ARBC unit by name, or salt stress or drought stress induction of an expression cassette, such features would be inherent in an ABA-inducible promoter.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (In: *Frontiers in Biology: The Challenges of Biodiversity, Biotechnology and Sustainable Agriculture*. C.H. Chou & K.T. Shao, eds, Academia Sinica, Taipei, pp. 115-122, 1998, Applicant's IDS).

The claims are drawn to a method for conferring tolerance to salt stress and drought stress in a monocotyledonous plant comprising transforming a plant with a salt stress or drought stress inducible expression cassette comprising at least one ABRC unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants.

Cheng et al. teach the production of water stress or salt stress tolerant transgenic rice plants that comprise one or two of the following genes: a barley late embryogenesis abundant protein gene (*Hva1*), a cold and salt stress resistance gene (*COR47*), a gene encoding a proline biosynthesis enzyme (*P5CS*) (Abstract). Constitutive or ABA-inducible promoters were used to drive these genes (Abstract). Cheng et al. introduced three different plasmids containing ABA-inducible promoters into rice cells and regenerated transgenic plants there from. Two of these plasmids, pJPM001 and pJP21, comprised an ABRC1 ABRC unit, an *Act*-100P minimal *Act1*

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promoter, an *Hva1* DNA molecule that increases tolerance to salt stress and drought stress, and a DNA sequence encoding the selectable marker *bar* (page 118). The third plasmid comprised an ABRC1 ABRC unit, an *Act-100P* minimal *Act1* promoter, a *P5CS* DNA molecule that increases tolerance to salt stress and drought stress, and a DNA sequence encoding the selectable marker *bar* (pages 120-121).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of Wu et al. (Abstract 113, General Meeting of The International Program on Rice Biotechnology, September 15-17, 1997, Applicant's IDS) or Cheng et al. (In: Frontiers in Biology: The Challenges of Biodiversity, Biotechnology and Sustainable Agriculture. C.H. Chou & K.T. Shao, eds, Academia Sinica, Taipei, pp. 115-122, 1998, Applicant's IDS), in view of Applicant's admitted prior art.

The claims are drawn to a method for conferring tolerance to salt stress and drought stress in a monocotyledonous plant comprising transforming a plant with a salt stress or drought stress inducible expression cassette comprising at least one ABRC unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants. The claims are also drawn performing this method by means of microparticle bombardment mediated transformation, and by means of *Agrobacterium* mediated transformation.

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The teachings of Wu et al. and Cheng et al. are discussed *supra*.

Neither Wu et al. nor Cheng et al. specifically teach microparticle bombardment mediated transformation, or *Agrobacterium* mediated transformation.

Given that microparticle bombardment mediated transformation and *Agrobacterium* mediated transformation of monocotyledonous plants was known in the art at the time of Applicant's invention (specification pages 13-16), and given the success of Wu et al. and Cheng et al. in transforming a monocotyledonous plant with a salt stress or drought stress inducible expression cassette, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to employ microparticle bombardment mediated transformation or *Agrobacterium* mediated transformation, for the purpose of conferring salt stress or drought stress tolerance to a monocotyledonous plant, without any surprising or unexpected results. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al. (Plant Physiology, 1996, Vol. 110, pages 249-257) in view of Shen et al. (The Plant Cell, Vol. 8, pages 1107-1119, July 1996, Applicant's IDS), further in view of Applicant's admitted prior art.

The claims are drawn to a method for conferring tolerance to salt stress and drought stress in a monocotyledonous plant comprising transforming a plant with a salt stress or drought stress inducible expression cassette comprising at least one ABRC unit, a minimal promoter, and a DNA molecule that increases tolerance to salt stress and drought stress in plants. The claims

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are also drawn performing this method by means of microparticle bombardment mediated transformation, and by means of *Agrobacterium* mediated transformation.

Xu et al. teach a method of producing a stress tolerant transgenic rice plant by transforming a rice cell with a nucleic acid encoding the late embryogenesis abundant protein HVA1 (page 250 column 1 lines 17-20). Microparticle bombardment was used to transform rice cells with a plasmid comprising a first nucleic acid encoding HVA1 under the control of the rice actin 1 gene promoter, and a second nucleic acid encoding the *bar* selectable marker gene (page 250 column 2 *Production of Transgenic Rice Plants*, page 252 *Figure 1*). Transgenic rice plants were regenerated and shown to have increased levels of HVA1 protein as well as increased tolerance to water stress and salt stress (page 254 *Tables II, III and IV*, page 255 *Figure 4* and *Table V*).

Xu et al. do not teach the use of an expression cassette comprising at least one ABRC unit, or *Agrobacterium* mediated transformation.

Shen et al. teach expression cassettes comprising the ABRC of the *Hva1* gene. The ABRC of the *Hva1* gene conferred ABA inducibility to the *Amy64* minimal promoter operably linked to a GUS reporter gene (page 1111 *Figure 2*, page 1112 *Figure 3*, page 1113 *Figure 4*). Shen et al. teach the desirability of using their synthetic promotes to confer ABA-inducibility on the expression of transgenes that would enhance stress tolerance, since stress induces the synthesis of ABA, and since stress tolerance transgenes expression would be most useful to the plant under stress conditions (page 1116 column 2 last paragraph to page 1117 column 1 first paragraph).

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Given that *Agrobacterium* mediated transformation of monocotyledonous plants was known in the art at the time of Applicant's invention (specification pages 13-16), given the success of Xu et al. in conferring tolerance to salt stress and drought stress in a rice plant by using microparticle bombardment to transform a plant with a DNA molecule encoding the late embryogenesis abundant protein HVA1, and given the success of Shen et al. in conferring ABA inducibility to a minimal promoter by operably linking the minimal promoter to the ABRC of the *Hva1* gene, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to use a minimal promoter operably linked to an ABRC as taught by Shen et al. to express a DNA molecule that increases tolerance to salt stress and drought stress in plants as taught by Xu et al., for the purpose of conferring salt stress or drought stress tolerance to a monocotyledonous plant, without any surprising or unexpected results. The use of *Agrobacterium* mediated transformation would have been an obvious modification of experimental design parameters. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success. Thus, the claimed invention would have been *prima facie* obvious as a whole to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-18 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/107201 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. Claims 1-18 of the instant application differ from the claims of

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copending Application No. 09/107201 in that they require the nucleic acid encoding the stress tolerance protein to be operably linked to at least one ABRC unit and a minimal promoter.

Claims 14-18 of the instant application also differ in that they require the use of *Agrobacterium* mediated transformation, rather than microparticle bombardment mediated transformation.

ABRC units, minimal promoters, and the use of *Agrobacterium* mediated transformation were known in the art at the time of Applicant's invention, and their use in the methods of the instant invention would have been an obvious optimization of design parameters.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Claims 1-18 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/339364 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. Claims 1-18 of the instant application differ from the claims of

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compending Application No. 09/339364 in that they require the nucleic acid encoding the stress tolerance protein to be operably linked to at least one ABRC unit and a minimal promoter.

Claims 14-18 of the instant application also differ in that they require the use of *Agrobacterium* mediated transformation, rather than microparticle bombardment mediated transformation.

ABRC units, minimal promoters, and the use of *Agrobacterium* mediated transformation were known in the art at the time of Applicant's invention, and their use in the methods of the instant invention would have been an obvious optimization of design parameters.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the compending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the compending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 5,981,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-18 of the instant application require the nucleic acid encoding the stress tolerance protein to be operably linked to at least one ABRC unit and a minimal promoter. Claims 14-18 of the instant application also require the use of *Agrobacterium* mediated transformation, rather than microparticle bombardment mediated transformation. ABRC units, minimal promoters, and the use of *Agrobacterium* mediated transformation were known in the art at the time of Applicant's invention, and their use in the methods of the instant invention would have been an obvious optimization of design parameters.

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3-5, 11-12, 15, 46-55 and 72 of copending Application No. 09/107201. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-18 of the instant application require the nucleic acid encoding the stress tolerance protein to be operably linked to at least one ABRC unit and a minimal promoter. Claims 14-18 of the instant application also require the use of *Agrobacterium* mediated transformation, rather than microparticle bombardment mediated transformation. ABRC units, minimal promoters, and the use of *Agrobacterium* mediated

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transformation were known in the art at the time of Applicant's invention, and their use in the methods of the instant invention would have been an obvious optimization of design parameters.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/339364. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-18 of the instant application require the nucleic acid encoding the stress tolerance protein to be operably linked to at least one ABRC unit and a minimal promoter. Claims 14-18 of the instant application also require the use of *Agrobacterium* mediated transformation, rather than microparticle bombardment mediated transformation. ABRC units, minimal promoters, and the use of *Agrobacterium* mediated transformation were known in the art at the time of Applicant's invention, and their use in the methods of the instant invention would have been an obvious optimization of design parameters.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
May 20, 2002


PHUONG T. BUI
PRIMARY EXAMINER